REMARKS

Applicants have received and carefully reviewed the Office Action of the Examiner mailed July 12, 2005. Claims 48-75 remain pending. Claims 48 and 64 have been amended. Support for the amendments is found in the specification, claims, and drawings as originally filed. No new matter has been added. Reconsideration and reexamination are respectfully requested.

Rejection under 35 U.S.C. § 102(b)

Claims 48-50, 52, 54-59, 61, 62, 64-67, 69, 71-75, 77, and 78 are rejected as being anticipated by Hauser et al. (U.S. 5,385,574). Applicants respectfully traverse the rejection, to the extent that it is maintained.

Independent claim 48, as amended, recites that the subcutaneous electrically active canister and the subcutaneous electrode are adapted for delivery of electrical cardioversion-defibrillation energy between the subcutaneous electrically active canister and the subcutaneous cardioversion-defibrillation electrode. Also, independent claim 64, as amended, recites that the subcutaneous electrode serves as the opposite electrode from the canister, and that the subcutaneous electrically active canister and the subcutaneous electrode are adapted to deliver cardioversion-defibrillation energy between the canister and the electrode. Applicants submit that Hauser et al. do not teach or suggest a device as claimed in either of these independent claims.

Hauser et al. teach an implantable cardiac stimulation device having a canister and a lead containing a sensing tip electrode 36 and electrodes 28, 29. Hauser et al. teach implanting the lead transvenously such that electrode 28 is positioned in the right ventricle and electrode 29 is proximate the right atrium or the superior vena cava. See column 5, lines 47-54 and FIG. 6. Hauser et al. teach circuitry 18 and a programmable switch 16 as selecting any combination of three electrodes to deliver an electrical pulse to the heart, the three electrodes selected from the right ventricular electrode 28, pulse generator electrode surface 14 (on the canister) and superior vena cava electrode 42. The superior vena cava electrode 42 can be replaced by a subcutaneous electrode. See column 6, lines 1-9. Hauser et al. teach the switch being programmed to discharge the right ventricular electrode 28 against the superior vena cava electrode 42 or

subcutaneous electrode and/or the pulse generator electrode surface. See column 6, lines 14-17. Hauser et al. thus teach a device in which right ventricular electrode 28 is used in combination with the subcutaneous canister and/or the superior vena cava or subcutaneous electrode for delivering a shocking pulse to the heart.

In the embodiments taught by Hauser et al. that involve a subcutaneous electrode, the shocking pulse is still delivered between an electrode in the heart and a subcutaneous electrode. Hauser et al. do not teach or suggest a subcutaneous electrically active canister and a subcutaneous electrode that are adapted for delivery of electrical cardioversion-defibrillation energy between the subcutaneous electrically active canister and the subcutaneous cardioversion-defibrillation electrode, as in independent claim 48. Likewise, Hauser et al. do not teach or suggest a subcutaneous electrode that serves as the opposite electrode from a subcutaneous electrically active canister, and that the subcutaneous electrically active canister and the subcutaneous electrode are adapted to deliver cardioversion-defibrillation energy between the canister and the electrode, as in independent claim 64.

Additionally, there is no motivation, suggestion or guidance in Hauser et al. for one of ordinary skill in the art to modify the device of Hauser et al. to provide the claimed structure. Hauser et al. already provide electrode 28 positioned within the heart for the purpose of shocking the heart. Further, there is no indication or suggestion that the right ventricle electrode 28 or right atrium 29 electrode of Hauser et al. is adapted to deliver cardioversion-defibrillation energy to the heart from a subcutaneous position. Hauser et al. teach the electrodes 29, 28 as being positioned within the heart when delivering an electrical shock. Applicants submit that one of ordinary skill in the art would not expect such electrodes to be adapted to deliver cardioversion-defibrillation energy to the heart from a subcutaneous position.

Hauser et al. do not teach or suggest each and every element of independent claims 48 and 64, or the claims dependent thereon. Withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. § 103(a)

Claims 51, 53, 63, 68, 70, and 79 are rejected as being unpatentable over Hauser et al. Applicants respectfully traverse the rejection, to the extent that it is maintained. As discussed above, Hauser et al. do not teach or suggest the basic elements of independent claims 48 and 64, from which the above claims depend. Hauser et al. thus do not teach or suggest the elements of

the dependent claims, which include the elements of the independent claims from which they depend, and include further patentable subject matter. Withdrawal of the rejection is respectfully requested.

Claims 60 and 76 are rejected as being unpatentable over Hauser et al. in view of Bennett et al. (U.S. 5,331,966). Applicants respectfully traverse the rejection, to the extent that it is maintained. As stated above, Hauser et al. do not teach or suggest the basic elements of independent claims 48 and 64, from which claims 60 and 76 depend, and Bennett et al. do not provide what Hauser et al. lacks. For example, Bennett et al. do not teach or suggest a subcutaneous electrically active canister and a subcutaneous electrode that are adapted for delivery of electrical cardioversion-defibrillation energy between the subcutaneous electrically active canister and the subcutaneous cardioversion-defibrillation electrode, as in independent claim 48. Likewise, Bennett et al. do not teach or suggest a subcutaneous electrode that serves as the opposite electrode from a subcutaneous electrically active canister, and that the subcutaneous electrically active canister and the subcutaneous electrode are adapted to deliver cardioversion-defibrillation energy between the canister and the electrode.

Furthermore, the Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to add at least one sensing electrode to the canister of Hauser et al., as taught by Bennett et al. in order to provide a leadless orientation specific insensitive means for receiving electrical signals from the heart. Applicants respectfully traverse this assertion, to the extent that it is maintained.

Bennett et al. teach a sensing device with an endocardial lead 12 and electrodes 14, 16 residing within the right ventricle of the heart. See column 13, lines 12-19, and FIG. 1. Bennett et al. do not teach a subcutaneous lead with one or more sensing electrodes. Bennett et al. teach the sensing electrodes only present on the canister. The Examiner acknowledges that Hauser et al. teach sensing electrodes on the lead, but do not teach sensing electrodes on the canister. Each reference thus teaches sensing electrodes only present on one or the other of the lead or canister. Thus, even if one were to combine the teachings, one would not arrive at the claimed invention. Additionally, there is no motivation to modify the references to include such selecting means, because both references teach devices with sensing electrodes only on one component of the device, so there are not multiple sets of sensing electrodes to select from. Applicants submit that the combination of Hauser et al. and Bennett et al. do not teach or suggest each and every

element of the claims. For each of these reasons, withdrawal of the rejection is respectfully requested.

Claims 80-85 are rejected as being unpatentable over Dahl et al. (U.S. 5,300,106) in view of Anderson et al. (U.S. 5,447,521). Dahl et al. teach providing defibrillation pulses across first and second subcutaneous electrodes on a lead, where the electrode segments are sufficiently near one another to function in concert. See column 6, lines 7-12. Dahl et al. do not teach an electrically active canister. The Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Dahl et al. with an electrically active canister defibrillator in the pectoral region as taught by Anderson et al. in place of one of the subcutaneous electrodes because it would result in a more efficient system, a smaller size canister, eliminate the possible breakage of the subcutaneous electrode and reduce the number of implanted parts since the defibrillator case is a "free" electrode. Applicants respectfully traverse the rejection.

Applicants submit that there is no motivation for modifying the Dahl et al. method of implanting three close-set subcutaneous electrodes to include an electrically active canister according to Anderson et al. because Anderson et al. actually teaches away from such a method. Anderson et al. teach, with "CAN" referring to an electrically active canister, and "SUB" referring to a subcutaneous electrode, that "a pattern with CAN and SUB having opposite polarities is rejected because the current from one to the other would be remote from the heart and wasted." See column 5, lines 43-46. Anderson et al. thus specifically teach away from a method in which a subcutaneously implanted electrically active canister is used with a subcutaneous electrode having the opposite polarity. Independent claim 80 recites implanting a subcutaneous electrically active canister and a subcutaneous electrode that serves as the opposite electrode from the canister.

Additionally, Applicants have found no suggestion in either Dahl et al. or Anderson et al. that substituting the electrically active canister of Anderson et al. for one of the subcutaneous electrodes of Dahl et al. would result in a more efficient system. As stated above, such a substitution would appear to be ineffective according to Anderson et al. Further, Applicants do not understand how such a substitution would eliminate the possible breakage of the subcutaneous electrode and reduce the number of implanted parts. If this rejection is maintained, the Examiner is respectfully requested to provide an explanation of this.

Double Patenting Rejections

Claims 48-79 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21, 26, 28, 29, 31, 33, 34, 38, 45-48, 50, 54, 55, 57, 74-79, 81-87, 89, 90, 93, 94, 108, 110, 112, 114-116 and 118-121 of U.S. Patent No. 6,721,597. Claims 80-82 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-8, 19 and 20 of U.S. Patent No. 6,721,597. Claims 83-85 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-13, 15 and 18 of U.S. Patent No. 6,721,597.

Applicants do not concede the correctness of the above rejections. However, in the interest in furthering prosecution, Applicants have filed herewith a Terminal Disclaimer.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,
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By their Attorney,

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